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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,839	06/05/2006	Mordechai Deutsch	30024	3193

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EXAMINER	
EDWARDS, LYDIA E	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
08/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,839	DEUTSCH ET AL.	
	Examiner	Art Unit	
	LYDIA EDWARDS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-3,5-7,12,18,22,27,29,30,42,43,48,49,56,68,74,80,86,90,91,105,109,111,121,130,132,139,145,153,156,178,179,181,186 and 193.

Continuation of Disposition of Claims: Claims rejected are 1-3,5-7,12,18,22,27,29,30,42,43,48,49,56,68,74,80,86,90,91,105,109,111,121,130,132,139,145,153,156,178,179,181,186 and 193.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/11/2010, 5/25/2010, 6/6/2010, 6/14/2010 and 6/22/2010.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 6/7/2010 have been fully considered but they are not persuasive.

In response to applicant's arguments that Bochner does not disclose, teach, or suggest that the wells are configured to or formed to inhibit adhesion, the examiner respectfully disagrees. The wells of Bochner inherently inhibit adhesion. He teaches in each embodiment, the microorganisms (cells) to be tested are mixed in a suspension comprising a gelling agent, and then inoculated into a well, compartment, or other receptacle, which contains the biochemical(s) to be tested, along with a gel-initiating agent such as various cations. Upon contact of the gelling agent with the gel-initiating agent (e.g., cations), the suspension solidifies to form a viscous colloid or gel, with the organisms evenly distributed throughout (Col 14, lines 18-25). As interpreted by the examiner, the cells never actually adhere to and or touch the wall of the well but instead they remain encapsulated by the gel or the viscous colloid.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

In response to applicant's arguments that Kim does not disclose, teach, or suggest that the wells are configured to or formed to inhibit adhesion, the examiner respectfully disagrees. Kim discloses in Paragraph 139 where portions of the surface can be treated, conditioned, or coated with a substance that resists cell attachment.

In response to applicant's arguments that Kim does not disclose, teach, or suggest a surface having protuberances, or of removing cells from a biological sample by contacting the sample with said surface, the examiner respectfully disagrees. As interpreted by the examiner, Figure 1b discloses protuberances [150 and 160].

Furthermore, Kim discloses wherein the cells are allowed to attach to the support (surface) [140] and to grow to confluence. The walls of the micro-orifice [300] constrain the cell(s) and the cells take on the shape of the micro-orifice [300], e.g., circular. A test agent is applied through the micro-orifices [300] and is allowed to contact the cells. The first layer (surface) [150] is removed and the cells are observed. If the test agent affects cell movement, the cell will be "stuck" in place as-it was patterned and-may not change shape, i.e., it will remain circular if the patterning member had circular orifices. On the other hand, if the test agent does not effect cell movement, the cell will move away from its original patterned position and change shape from the patterned circular shape since the constraints of the first layer [150] had been removed. As interpreted by the examiner, Kim teaches cell migration after being contacted by [150].

In light of the cancelation of claim 13 and amendment of claim 91, the 112 2nd paragraph rejections have been withdrawn.

Claim Objections

Claims 22, 27, 109, and 111 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Regarding claims 22, 27, 109, and 111, the claims fail to further limit the structure of the device as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 43, ***"the interwell area"*** has not been defined by any dimension and is therefore indefinite.

Regarding Claim 48, the examiner is unclear as to what and how knife-edge defines the well structure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 42, 80, 86, 145, 153, and 156 are rejected under 35 U.S.C. 102(b) as being anticipated by Bochner et al. (US 5627045).

Regarding Claims 1 and 5, 42, 80, and 86, Bochner et al. ('045) teaches a device for holding living cells, the device comprising a carrier [100] having a plurality of juxtaposed wells [130] disposed on a surface [120] each well configured to hold at least one living cell, the device characterized in that the insides of said wells are configured to or formed to inhibit adhesion of living cells held in said wells (Col 8, line 35-Col 9, line 9 and Figures 1-4).

Regarding Claim 2, Bochner et al. ('045) teaches wherein the inside of said wells comprises a material selected from the group consisting of a gel (Col 8, line 65-Col 9, line 9).

Regarding Claim 145, Bochner et al. ('045) teaches method of making a chip-device comprising: providing a carrier having a plurality of wells disposed on a surface, each well configured to hold at least one living cell; and coating the inside of said wells with a layer of a material configured to influence proliferation of living cells held in said wells (Col 8, line 65-Col 9, line 34; Example 4).

Regarding Claims 153 and 156, Bochner et al. ('045) teaches a method of manipulating cells, comprising: providing a plurality of wells of a well-bearing component, each well configured to hold at least one living cell; holding a plurality of living cells in a plurality of said

wells; placing a gellable fluid in proximity with said surface so as to fill said plurality of wells; and gelling said gellable fluid so as to form a gel cover (Col 8, line 65-Col 9, line 34).

The examiner interprets the gel matrix of Bochner to be a cover once produced, trapping the suspended microorganisms.

Claims 1-3, 5-7, 35, 42-43, 49, 68, 74, 86, 121, 130, 132, 139, 145, 186 and 193 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. (US 20030030184).

Regarding Claims 1, 5, 42, 86, Kim et al. ('184) teaches a device for holding living cells, the device comprising a carrier [100] having a plurality of juxtaposed wells [170] disposed on a surface [140] each well configured to hold at least one living cell, the device characterized in that said wells are configured to influence the proliferation of living cells held in said wells (Paragraphs 135 and 215 and Figures 1).

Regarding Claims 2-3, Kim et al. ('184) teaches wherein said carrier is substantially made of a material selected from the group consisting of a polydimethylsiloxane, an elastomer and silicon rubber (Paragraphs 138 and 143).

Regarding Claims 6-7, Kim et al. ('184) teaches wherein the carrier can be formed by molding (Paragraph 194). Therefor the device is capable of deforming in at least one dimension and changing the size of the wells.

Regarding Claim 35, Kim et al. ('184) teaches wherein the inside of said wells is configured to delay adhesion of living cells thereto (Paragraph 214).

Regarding Claims 43 and 49, Kim et al. ('184) teaches wherein the dimensions of said wells are less than about 200 microns (Paragraph 142).

Regarding Claim 68, Kim et al. ('184) teaches protuberances protruding from said surface between two adjacent wells (Paragraph 135; Figures 1b:160a; 1b:150a).

Regarding Claim 74, Kim et al. ('184) teaches at least one wall protruding from said surface, said at least one wall circumscribing at least one area of said surface where the points of the top edge of said wall define a plane (Figures 1 and 1b).

Regarding Claim 86, Kim et al. ('184) teaches a carrier comprising a first layer [150] of a first material resting on top of a second layer [160] of a second material, the carrier having a plurality of wells [170] disposed on an upper surface of said first layer each of said plurality of wells configured to hold at least one living cell, wherein the bottom of said plurality of wells is said second layer (Paragraph 132 and Figures 1, 1a and 2a).

Regarding Claims 121, 130, 132 and 139, Kim et al. ('184) teaches a method of making a chip-device of claim 1 comprising: providing a template having a negative of features of said surface of said carrier; contacting said template with a precursor material so as to create said

features in said precursor material; and fixing said features in said precursor material so as to fashion said carrier (Paragraphs 190-199).

PDMS is viscoelastic, meaning that at long flow times (or high temperatures), it acts like a viscous liquid, similar to honey (of which the examiner interprets to be the same as a gellable fluid) which can flow to cover the surface and mold to any surface imperfections. However at short flow times (or low temperatures) it acts like an elastic solid, similar to rubber.

Regarding Claim 145, Kim et al. ('184) teaches a method of making a chip-device comprising: providing a carrier having a plurality of wells disposed on a surface, each well configured to hold at least one living cell; and coating the inside of said wells with a layer of a material configured to influence proliferation of living cells held in said wells (Paragraphs 135, 206, and 215).

Regarding Claim 186, Kim et al. ('184) teaches a method of growing cells comprising: providing a well-bearing device; holding at least one living cell in a well of said well-bearing device (Figure 1); and increasing the size of said well so as to provide an increased space for proliferation of said cell (Paragraph 208).

Regarding Claim 193, Kim et al. ('184) teaches a method comprising: providing a well-bearing device, said well-bearing device having: a plurality of wells disposed on a surface, each well configured to hold at least one cell; and a plurality of protuberances protruding from said

surface contacting the biological sample with said surface so as to remove cells from the biological sample (Paragraphs 135, 208 and Figures 1 and 1b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 and 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 20030030184) as applied above to claim 1, further in light of Sanghera et al. (US 5525800) and Hahn et al. (US 20030017079).

Regarding Claims 12 and 90, Kim et al. ('184) teaches a chip-device for holding living cells, the device comprising a carrier [100] having a plurality of wells [170] disposed on a surface each well configured to hold at least one living cell, the device characterized in that said carrier is made of PDMS, a material having an index of refraction similar to that of water (Paragraphs 138 and 143).

PDMS is well known on the art to have a refractive index of about 1.4 as evidenced by Sanghera et al. in Col 8, lines 54-56 which is close to the refractive index of water which is equal to 1.33 as evidenced by Hahn et al. in Paragraph 19.

Regarding Claim 91 Kim et al. ('184) teaches a chip-device for holding living cells, the device comprising a carrier [100] having a plurality of wells [170] disposed on a surface each well configured to hold at least one living cell, the device characterized in that said carrier is made of a material having an index of refraction similar to that of water (Paragraphs 138 and 143).

PDMS is well known on the art to have a refractive index of about 1.4 as evidenced by Sanghera et al. in Col 8, lines 54-56 which is close to the refractive index of water which is equal to 1.33 as evidenced by Hahn et al. in Paragraph 19.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim with a material having an index of refraction less than about 1.4, in order to optimize the carriers ability to identify the particular living cell, confirm its purity or measure its concentration via the use of an optical system.

Claims 18, 22, 27, 29-30, 105, 109, and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 20030030184) as applied above to claim 1, further in view of Ravkin et al. (US 2003/0059764).

Regarding Claims 18, 22, 27, and 29-30, Kim et al. ('184) teaches the device of claim 1 except for wherein the carrier and cover are made of gel.

Ravkin ('764) teaches a cell analysis system wherein carriers or portions thereof, such as an outer layer (cover) or an internal region also may be made from a gel (Paragraph 90).

The examiner interprets the outer layer described by Ravkin to be equivalent to a cover.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim with gel portion as taught by Ravkin in order to provide a suitable adhesion layer for cells and cell analysis materials or provide a better storage or handling characteristics.

With respect to the intended use limitations, the device disclosed by Kim and Ravkin is structurally the same as the instantly claimed and is capable of providing the operating

conditions listed in the intended use section of the claim. Note statements of intended use carry no patentable weight when the structure of the Claim has been met by the prior art reference.

Regarding Claims 105, 109, and 111, Kim et al. ('184) teaches a device for holding living cells, the device comprising a carrier [100] having a plurality of juxtaposed wells [170] disposed on a surface [140] each well configured to hold at least one living cell, the device characterized in that said wells are configured to influence the proliferation of living cells held in said wells (Paragraphs 135 and 215 and Figures 1). Kim also discloses wherein the device comprises at least one cover (Paragraph 28).

Kim does not disclose wherein the said cover is made of gel.

Ravkin ('764) teaches a cell analysis system wherein carriers or portions thereof, such as an outer layer (cover) or an internal region also may be made from a gel (Paragraph 90).

The examiner interprets the outer layer described by Ravkin to be equivalent to a cover.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim with gel portion as taught by Ravkin in order to provide a suitable adhesion layer for cells and cell analysis materials or provide a better storage or handling characteristics.

With respect to the intended use limitations, the device disclosed by Kim and Ravkin is structurally the same as the instantly claimed and is capable of providing the operating conditions listed in the intended use section of the claim. Note statements of intended use carry no patentable weight when the structure of the Claim has been met by the prior art reference.

Claims 178-179 and 181 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bochner et al. (US 5627045) as applied above to claim 153, further in view of Kim et al. (US 20030030184).

Regarding Claims 178-179 and 181, Bochner ('045) teaches the method of claim 153 as rejected above except for isolating at least one cell by excising said at least one said cell from said well-bearing component and contacting an active entity-containing fluid with said gel cover.

Kim ('184) teaches contacting an active entity-containing fluid with the well bearing device (Paragraph 205, 208 and 214). Kim also teaches wherein the cells were removed from the macro-wells (Paragraph 293).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bochner with the method of adding a test solution/agent as taught by Kim in order to provide a method of identifying microbes, methods of screening for the activity of drugs, methods for detecting toxic substances and methods for detecting intercellular reactions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYDIA EDWARDS/
Examiner
Art Unit 1797

LE

/Walter D. Griffin/
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